REMARKS / ARGUMENTS

The action by the Examiner in this application, together with the references cited, has been given careful consideration. Following such consideration, claims 1, 7, and 12 have been amended, claims 26-31 have been added, and claims 2-6, 8-11, and 13-25 remain unchanged. It is respectfully requested that the Examiner reconsider the claims in their present form, together with the following comments, and allow the application.

As the Examiner well knows, the present invention relates to a container for holding medical instruments to be microbially deactivated in a reprocessor. More specifically, the present invention relates to a valve disposed in the container.

During reprocessing, medical instruments are microbially deactivated, i.e., sterilized. Following reprocessing, it is important that the sterilized instruments remain sterile until they are used. To ensure that the instruments remain sterile, the container of the present invention is dimensioned such that all surfaces of the container that might be exposed to the medical instruments after reprocessing are exposed to a liquid deactivation compound during reprocessing. Thus, all surfaces of the container that are in communication with the instruments after reprocessing are microbially deactived during reprocessing.

The container of the present invention includes a tray and a lid. The tray includes a bottom wall and a continuous side wall extending to one side of the bottom wall that define a cavity for receiving instruments. The tray also has a fluid inlet and a fluid outlet that each include a mounting plate. Each mounting plate has an opening formed therein, and is disposed in the bottom wall. The opening defines a surface that surrounds the opening and communicates with the cavity.

Each inlet and outlet has a flexible valve element formed of a resilient flexible polymeric material disposed therein. The flexible valve element is preferably *integrally formed as a single piece.* The valve element includes a central body portion (first portion) and an outer, annular, flanged ring portion (second portion). The central body portion and the flanged ring portion are connected by a plurality of radially extending arm portions. The flanged ring portion is dimensioned to be fixedly attached to the tray.

The flexible valve element is movable relative to the tray between a normally closed position and an open position. In particular, the central body portion and the radially extending arms are movable relative to the tray between the closed position and the open position. When the container is inserted into the reprocessor, the central body portion comes into contact with a mechanical actuator on the reprocessor that moves the central body portion to the open position. In the open position, the central body portion is disposed away from the mounting plate toward the cavity. When the container is removed from the reprocessor, the action of the resilient arm portions moves the central body portion to the normally closed position. When in the closed position, the central body portion engages, or is "seated," against the surface of the mounting plate that surrounds the opening.

According to one aspect of the present invention, all surfaces of the valve element that are exposed to the interior of the container when the central body portion is in the closed position are exposed to a liquid deactivating composition during a deactivation process when the body portion is in an open position. As best seen in FIG. 13 of the application, when the central body portion is in the open position, surfaces of the valve element, except for the surface contacted by the mechanical actuator, are exposed to the liquid deactivation composition. When the central

body portion is in the closed position, the surface that contacts the mechanical actuator is outside of the container and therefore does not pose a risk for recontaminating medical instruments contained within the container.

It is respectfully submitted that none of the cited references teaches, suggests, or shows a container for holding medical instruments as presently set forth in the claims or the advantages thereof.

In response to the Examiner's rejections, the claims have been amended to define more clearly the patentable invention Applicants believe is disclosed herein. Claims 1, 7, and 12 have been amended to indicate that the flexible valve element is "integrally formed."

New independent claim 26 has been added along with new dependent claims 27-31. Claim 26 is directed to a container for holding items to be microbially deactivated in a reprocessor that includes a tray having a bottom wall and a continuous side wall that define a cavity. An opening is defined in the bottom wall. The opening defines a surface that surrounds the opening. The surface communicates with the cavity. A valve element is movable by a mechanical actuator between an open position and a closed position. As required by claim 26, when the valve element is in the open position, the valve element is disposed away from the surface toward the cavity. When the valve element is in the closed position, the valve element engages the surface.

Claims 1-13 and 16-23 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,552,115 to Malchesky in view of U.S. Patent No. 4,445,551 to Bond et al.

The Malchesky reference teaches a decontamination unit for receiving a tray having an attachable lid. The tray has a side wall. Tubing members are connected to a check valve that is connected to an elastomeric grommet, or connector, disposed in the side wall.

The Bond et al. reference teaches a quick-disconnect coupling and valve assembly. The valve assembly includes a spout and a valve member disposed therein. *The valve member and the spout are separate elements and are not integrally formed.* The valve member is axially and slidably movable within the spout between an open position and a closed position. The valve member has openings formed in one end that extend past the spout when the valve member is in the open position. When the valve member is in the closed position, the valve member is surrounded by the spout such that the openings are blocked by the spout.

Regarding claims 1, 7, and 12, neither the Malchesky reference nor the Bond et al. reference teaches, suggests, or shows an integrally formed flexible valve element having a first portion movable relative to said tray and a second portion fixed relative to said tray as required by claims 1, 7, and 12. Further, neither reference teaches a valve wherein all surfaces that are exposed to medical instruments following reprocessing, are exposed to a liquid deactivating agent during reprocessing.

Referring now to claim 26, neither the Malchesky reference nor the Bond et al. reference teaches, suggests, or shows a valve element having an open position to allow fluid to flow through an opening where the opening defines a surface that communicates with the cavity. Neither reference teaches, suggests, or shows a valve element disposed away from the surface that surrounds the opening and toward the cavity when the valve element is in the open position.

Further, neither reference shows a closed position sealing the opening where the valve element engages the surface that surrounds the opening.

To summarize, for medical instruments to remain microbially deactivated, all surfaces that might be exposed to the medical instruments must also be microbially deactivated. In this regard, valves having sliding structures, e.g., the valve disclosed in the Bond et al. reference, have surfaces that are not exposed to a liquid deactivation composition. Therefore, the valve disclosed in the Bond reference is not suitable and does not ensure that the internal region of the container and the medical instruments therein remain sterile.

The prior art made of record and not relied upon has also been reviewed. It is respectfully submitted that none of these additional references teach or suggest the applicant's invention as defined by the present claims.

In view of the foregoing, it is respectfully submitted that the present application is now in proper condition for allowance. If the Examiner believes there are any further matters which need to be discussed in order to expedite prosecution of the present application, the Examiner is invited to contact the undersigned.

If there are any fees necessitated by the foregoing communication, please charge such fees to our Deposit Account No. 50-0537, referencing our Docket No. ST8725US.

Respectfully submitted,

Date: **June 23, 2006**

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I hereby certify that this correspondence (along with any paper referenced as being attached or enclosed) is being deposited on the below date with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to MAIL STOP RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date: **June 23, 2006**

Laura K. Cahill